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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/668,792	09/23/2003	Bernard E. Cabana	4354-110	4322

23448 7590 12/29/2010

INTELLECTUAL PROPERTY / TECHNOLOGY LAW
PO BOX 14329
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EXAMINER	
SPIVACK, PHYLLIS G	
ART UNIT	PAPER NUMBER
1614	
MAIL DATE	DELIVERY MODE
12/29/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/668,792	CABANA ET AL.	
	Examiner	Art Unit	
	Phyllis G. Spivack	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 November 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,44-49,52-57 and 59-61* is/are pending in the application.

4a) Of the above claim(s) *44-48* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5, 49,52-57, 59-61* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

The finality of the last Office Action is withdrawn. Applicants' Response filed November 30, 2010 is acknowledged. Claims 1-5, 44-49, 52-57 and 59-61 are pending. Claims 44-48 remain withdrawn from consideration by the Examiner, 37 CFR 1.142(b), as drawn to non-elected inventions. All of the claims that are presently under consideration are drawn to compositions.

The present application is afforded an effective date of September 23, 2003. Provisional application 60/412,958 fails to recite the ranges herein claimed.

The rejection set forth in the last Office Action is withdrawn. The following rejection constitutes the only rejection presently applied to the instant claims.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-5, 49, 52-57 and 59-61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rose et al., U.S. Patent 6,316,433, in view of Remington's Pharmaceutical Sciences, and as evidenced by Yamane et al., U.S. patent 4,983,602.

Rose teaches single-dose oral administration of compositions comprising rifalazil in an amount of about 1 mg. An amount of 5 mg is administered in Example 1, column 32. The recitation "about 1" mg of rifalazil reasonably encompasses an amount of 0.8 mg. See the Abstract and claims 1, 11 and 16 in columns 33- 34. Motivation to administer a very low dose of rifalazil flows from its documented probability of causing severe adverse reactions and secondary symptoms. See column 4, lines 38-52. Pharmaceutical compositions comprising rifalazil are well established in the art. See U.S. Patent 4,983,602, column 12, line 58, to column 13, line 10.

Remington provides motivation to prepare a pharmaceutical formulation for oral administration comprising an antibiotic having first and second dosages with a higher amount of active antibiotic in the first dosage unit, as required by instant claim 49. Loading doses are used in many drug regimens when an urgent need exists to achieve a drug steady state. Remington is properly applied as a secondary reference to show a dosing regimen wherein a higher amount of active antibiotic, i.e., in a loading dose regimen, is dispensed in a first dosage to achieve a therapeutic drug concentration quickly. Such loading doses, as taught by Remington, reflect conventional practice in that the first dose has a higher amount of drug and is followed by a second lower dose, considered to be a maintenance dose.

Claim 49 recites "providing instructions for the use of said formulation," and the use is as an antibiotic. However, the instant composition claims do not have any structural differences from the prior art compositions. Therefore, there is no patentable distinction between the claimed invention and the prior art compositions. The

pharmaceutical compositions that are suggested by Rose are capable of performing the same antimicrobial use as those instantly claimed.

Claims 53-57 and 59-61 are drawn to compositions having instructions for administration. All pharmaceutical preparations that are dispensed to a patient are packaged in pharmaceutical containers along with instructions for administration. The mere placement of instructions within a formulation comprising rifalazil would have been within the general knowledge of one of ordinary skill in the art at the time of the invention. Such a person would have been motivated to do so to promote proper use of the formulation to patients in need thereof and to facilitate patient compliance with a prescribed regimen. Applicant is not entitled to patent a known product by simply attaching a set of instructions to that product. See *In re Ngai*, 367 F.3d 1336, 70 U.S.P.Q.2d 1862 (Fed. Cir. 2004).

A unit dosage is a finite, discrete drug entity having a specific amount of that drug. Such packaging is entirely conventional. Providing such a formulation in a portable container, or in unit dose packaging, that can be transported to allow for convenient dosing, is conventional.

The determination of optimal doses is well within the purview of those skilled in the art through no more than routine experimentation. See *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233,235 (CCPA 1955) and MPEP 2144.05(II).

Intended use confers no patentable weight to composition claims. A pharmaceutical composition must be both new and unobvious to one skilled in the art. See MPEP 2112 and *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed.

Cir. 1990). "Products of identical chemical compositions cannot have mutually exclusive properties." A chemical composition and its properties are inseparable. A pharmaceutical composition must be both new and unobvious to one skilled in the art.

In view of the combined teachings of the prior art, one skilled in the art of formulation chemistry would have been motivated to prepare unit dose packaging of the drug rifalazil in an amount between about 1-5 mg/unit. According to Remington, packaging of pharmaceutical agents as unit doses, along with instructions thereto, comprising a loading dose, followed by a second, lower dosage unit, is conventional therapeutic practice.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Phyllis G. Spivack whose telephone number is 571-272-0585. The Examiner can normally be reached from 10:30 to 7 PM.

If attempts to reach the Examiner by telephone are unsuccessful after one business day, the Examiner's supervisor, Ardin Marschel, can be reached 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

December 27, 2010

/Phyllis G. Spivack/
Primary Examiner, Art Unit 1614